

Attorney Docket No.: KBI-0015  
Inventors: Ranganathan, Natarajan  
Serial No.: 10/689,359  
Filing Date: October 20, 2003  
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#### **REMARKS**

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. Claims 1, 8 and 9 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### **I. Rejection of Claims Under 35 U.S.C. §112**

Claim 1, and claims 2-7 because they are dependent upon claim 1, have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, claim 1 is suggested as being unclear as it recites a composition comprising, in part, "about 47% to about 82% of at least one carbohydrate ingredient". The Examiner suggests that it is unclear whether the numbers are a comparison to the entire composition or to the carbohydrate ingredient. Applicant has amended claim 1 to clarify the composition and respectfully requests that this rejection be withdrawn.

#### **II. Double Patenting**

Claim 10 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,706,287. Applicant has filed herewith a terminal disclaimer in compliance with 37 CFR 1.321(c) and therefore respectfully requests that this rejection be withdrawn.

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### III. Rejection of Claims Under 35 U.S.C. §103

Claims 1-3 and 6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,902,578 (Halpin-Dohnalek et al.).

Claims 1, 3-6 and 8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,085,874 (Jungvid).

Claims 1, 3-5, 7, 9 and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,744,134 (Paul).

Claims 1, 3-5, 7, 10 and 11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,518,740 (Costanzo et al.).

It is suggested that the cited references teach the compositions of the instant invention for use in maintaining GI health and restoring GI health. It is suggested that while the cited references do not teach the specific amounts of each component as recited in the claims, a person of ordinary skill would have a reasonable expectation of success in making the compositions of the referenced teachings with the instant recited amounts because the cited references teach that the composition of their mixture can be varied. The Examiner suggests that it would have been routine in the art to optimize the amounts of each component in order to optimize the nutritional value of the mixture. Applicant respectfully traverses these rejections.

Applicant has appreciated that by providing high numbers (e.g., 5 billion to 20 billion cfu) of *viable* bacteria in the presence of a food composed of the claimed ingredients at the claimed amounts, greater populations of probiotic bacteria can be

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achieved to colonize the gastrointestinal tract thereby restoring gastrointestinal health and alleviating symptoms of uremia. See page 3, lines 15-19, and page 13, lines 22-28. The cited prior art references neither teach nor suggest bacterial levels of the instant compositions nor is there any appreciation in the prior art references as to preserving bacterial viability. In contrast, the instant specification teaches "light, heat, oxygen, and moisture content will adversely affect the viability of the probiotic bacteria" (page 12, lines 30-31) and edible fats in the range of about 2% to about 12% (paragraph bridging pages 16 and 17) and low moisture content (*i.e.*, water activities of less than about 0.47; page 19, lines 15-17) maintain a viable population of bacteria. In this regard, more viable bacteria are consumed in the claimed foods and at a much lower dosage than are consumed in a pill or powder supplement, as bacteria in these forms are prone to loss in viability (see page 13, lines 4-7, and page 14, lines 15-26). Thus, ingredients of the instant foods and their respective amounts are critical for achieving delivery of viable bacteria at particular doses. In an earnest effort to impart the unique properties of the instant food compositions, Applicant has amended the claims to indicate that the nutritional foods or nutritional products have a water activity of less than about 0.47. Because the prior art references fail to teach or suggest this feature in a nutritional food or nutritional product and further fail to teach or suggest the impact of water activity and particular food ingredients (*e.g.*, edible fats) on providing 5 billion to 20 billion cfu of viable bacteria, these references fail to make obvious the instant invention. It is therefore

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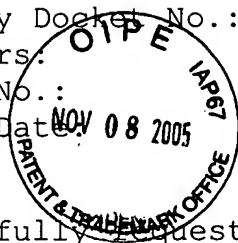
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respectfully requested that these rejections be reconsidered and withdrawn.

#### IV. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Jane Massey Licata".

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